

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-6, 8-14, and 17-24 are pending in the application, with claims 1 and 17 being the independent claims. Claims 1-6 and 8-14 are sought to be amended, claims 7 and 15-16 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Applicants reserve the right to file one or more divisional applications for the subject-matter canceled. New claims 17-24 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Support for the amended claims 1-6 and 8-14, and new claims 17-23 can be found in the specification and claims as originally filed. Specifically, support for the amendments in claim 1 can be found, *inter alia*, in original claim 7 and at page 2, line 26, at page 6, lines 15-22, and at page 32, lines 16-23.

Claim 3 has been amended by adding the phrase "a combination" to make the claim more clear. Further more, items f, p, cc, rr, zz, fff, lll, ttt, vvv, and pppppp have been deleted because of double inclusion. For the same reason, claim 14 has been amended by deleting items w and z. Applicants submit that no new matter has been introduced into claim by these amendments since deletion of individual members of Markush expression does not constitute new matter. See, *In re Johnson and Farnham*, 194 U.S.P.Q. 187 (C.C.P.A. 1977).

Support for new claim 17 is found, *inter alia*, at page 2, lines 23-27, at page 5, lines 3, at page 6, line 29, at page 7, line 29, at page 31, lines 28-30, and at page 32, lines

16-21. Support for claim 18 can be found, *inter alia*, at page 6, line 29 of the specification as originally filed. Claim 19 is supported by the original specification at page 7, line 4. Claim 20 is supported at page 7, lines 8-12 of the original specification. Claim 21 is supported by page 7, line 12. Support for claim 22 can be found in original claim 2. The limitation of Claim 23 is an inherent feature of the disclosure and invention of claim 17. Examples 7 and 8 disclose embodiments having the features of claims 17 and 23. Claim 24 is inherently disclosed by these same examples.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Objection to the Specification***

The Examiner has objected to the specification because of the use of trademarks. The Examiner states that trademarks should be capitalized where they appear and that they should be accompanied by the generic terminology. The Examiner further requires that the ingredients contained in the PROPOFLO™ and RAPINOVET™ at the time of the invention should be listed. Applicants respectfully traverse this objection.

It is respectfully submitted that the trademarks used in the application have already been properly identified by a proper trademark symbol ® or ™. Therefore, it is not necessary to capitalize the trademarks. Further, the ingredients contained in PROPOFLO™ and RAPINOVET™ at the time of the invention have already been listed

in the original specification at page 2, lines 6-13 and at page 2, lines 14-19, of the originally filed specification, respectively.

Reconsideration and withdrawal of the objection to the specification is respectfully requested.

***Rejections under 35 U.S.C. § 102***

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic v. Genentech, Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991).

***I. Carpenter et al. (U.S. Patent No. 6,150,423)***

The Examiner has rejected claims 1 and 2 under 35 U.S.C. § 102(a) as allegedly being unpatentable by Carpenter *et al.* (U.S. Patent No. 6,150,423). Applicants respectfully traverse this rejection.

The Examiner states that Carpenter *et al.* disclose an aqueous composition comprising propofol (column 2, lines 41+) and one or more excipients, for example benzalkonium chloride and benzethonium chloride (column 3, line 56+).

Applicants have amended claim 1 to require that the composition is stored in a container having a means for dispensing the composition; and that the total propofol

degradants of the solution when maintained at 25 °C, 40 °C, or 60 °C for 4 weeks are present in an amount of less than 5% (w/v) of the composition. It is respectfully submitted that Carpenter *et al.* do not describe any composition as claimed in amended claim 1 and, thus, do not describe each and every element of claim 1. Therefore, the reference does not anticipate claim 1. It follows that claim 2, that is dependent from claim 1, is not anticipated by the reference. Additionally, there is no motivation suggested by the art of record to modify the Carpenter formulations to arrive at the claimed invention.

Further, it is respectfully submitted that Carpenter *et al.* do not anticipate claim 17.

In view of the above, it is respectfully submitted that Carpenter *et al.* do not anticipate any of the present claims. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(a) of claims 1 and 2 are respectfully requested.

## ***II. Glen et al. (U.S. Patent No. 4,798,846)***

The Examiner has rejected claims 1 and 3 under 35 U.S.C. §102(a) as being unpatentable by Glen *et al.* (U.S. Patent No. 4,798,846). Applicants respectfully traverse this rejection.

The Examiner alleges that "Glen discloses composition [*sic*] propofol (claim 1) [*sic*] is selected from the group consisting "Cremaphor" EL column 6 line 24 which is item (a) of claim 3."

As discussed above, Applicants have amended claim 1 to require that the composition is stored in a container having a means for dispensing the composition; and

that the total propofol degradants of the solution when maintained at 25 °C, 40 °C, or 60 °C for 4 weeks are present in an amount of less than 5% (w/v) of the composition. Glen *et al.* do not describe any composition claimed in amended claim 1. Therefore, it is respectfully submitted that Glen *et al.* do not anticipate the composition as claimed in amended claim 1 at least because the reference does not describe each and every element of claim 1. Additionally, there is no motivation suggested by the art of record to modify the Glen *et al.* formulations to arrive at the claimed invention.

Claim 3 is dependent from claim 1 and, thus, is not anticipated by Glen *et al.*

Further, is respectfully submitted that Glen *et al.* do not anticipate new claim 17.

In view of the above, it is respectfully submitted that Glen *et al.* do not anticipate any of the present claims. Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(a) of claims 1 and 3 are respectfully requested.

### ***Double Patenting***

The Examiner has provisionally rejected claims 1-16 under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claims 1-16 of copending Appl. No. 10/677,747. Applicants respectfully traverse the rejection of claims as amended.

Applicants have amended claim 1 and canceled claims 7 and 15-16. It is respectfully requested that the Examiner reconsider and withdraw the rejection of claims 1-16 under 35 U.S.C. § 101.

***Supplemental Information Disclosure Statement***

Applicants direct the Examiner's attention to U.S. Published Appl. No. US 2005/0009731 A1, published January 31, 2005, submitted herewith. The published application includes claims directed to a sterile, parenteral, propofol composition stored in a container having a closure inert to propofol; i.e. a stored propofol composition exhibiting reduced propofol degradation compared to propofol compositions stored in a container depending upon the closure of the container. Applicants' claims 17 and 23 are substantially similar and may be directed to the same patentable invention. Claim 24 has been copied from the published application.


***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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